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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,730	01/02/2002	Robert M. Abrams	269/106 (cont.)	3733

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EXAMINER	
SHUKLA, RAM R	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,730	ABRAMS ET AL.	
	Examiner	Art Unit	
	Ram R. Shukla	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-60* is/are pending in the application.

4a) Of the above claim(s) *42,45 and 47-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-41,43,44,46 and 53-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This application is a continuation of 09/351,769.

2. Applicant's election of the invention of group I, claims 32-37, 40, 41, 43, 44, 46, and 53-60 in the reply filed on 4-12-04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). It is noted that applicants indicated that claims 38 and 39 were not addressed in the restriction requirement. The inadvertent error is regretted and as suggested by the applicants, the claims being dependent on claim 32 have been included in all the groups. Accordingly, the elected invention of group I contains claims 32-41, 43, 44, 46 and 53-60.

3. Claims 42, 45, and 47-52 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4-12-04.

4. Claims 32-41, 43, 44, 46 and 53-60 drawn to a composition comprising a polymer-forming, or dissolved polymeric, biodegradable material and a biologically active component wherein the biological component is a protein or peptide is under consideration.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 32-35, 38-4144, 46, 53-59-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Okada et al (US Patent 5,202,352).

Okada et al teaches a precursor composition that comprises different compositions, such as oils, salts of metals, wax, or synthetic or natural polymers, that include polypeptides, polysaccharides, poly-fatty acid esters, poly-amino acids, polyaldehydes, polyvinyl polymers, copolymer of lactic acid and glycolic acid etc. and a biologically active compound to from emboli in the vascular system (see claims 10-12) and the description in columns 7-9). The art also teaches molecular weight of the polymer to be in the range of 1,000 to 100,000 and concentration to be in 1 to 80% range (columns 7-11). The art also teaches that the composition could be administered via catheter (see lines 1-25 in column 11) and different solvents.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 32-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al (US Patent 5,202,352) in view of Cragg et al[1] (US 6,558,367 B1, May 6, 2003), Whalen et al (6,531,111 B1, March 11, 2003), Cragg et al[2]

(6,146,373, 14 Nov 2000), Greff et al (6015541, 18 Jan 2000), Murayama et al (5,891,192, 6 April 1999).

Okada et al teaches a precursor composition that comprises different compositions, such as oils, salts of metals, wax, or synthetic or natural polymers, that include polypeptides, polysaccharides, poly-fatty acid esters, poly-amino acids, polyaldehydes, polyvinyl polymers, copolymer of lactic acid and glycolic acid etc. and a biologically active compound to from emboli in the vascular system (see claims 10-12) and the description in columns 7-9). The art also teaches molecular weight of the polymer to be in the range of 1,000 to 100,000 and concentration to be in 1 to 80% range (columns 7-11). The art also teaches that the composition could be administered via catheter (see lines 1-25 in column 11) and different solvents. The art does not teach a composition comprising fibronectin.

At the time of the invention, arts of record (Cragg et al[1], Cragg et al[2] , Whalen et al, Greff et al, Murayama et al) taught embolizing compositions that comprised a precursor composition, a biocompatible solvent and a therapeutic composition. These arts also taught different polymers, which could be biodegradable or non-biodegradable polymers (see e.g. columns 5-6 in Greff et al, columns 5-6 in Whalen et al, columns 12-13 in Cragg et al[1]). The arts also taught using catheter for delivery of the composition (e.g. Cragg et al[1]). It is noted that the embolizing compositions were used for delivery therapeutic compositions comprising a therapeutic protein or a radioisotope or other agents. Further, the art of record taught protein coating of occlusion coils for better adhesion to vascular cells and adhesion. For example, Murayama et al taught coating the occlusion coils with adhesion proteins, such as fibronectin (see column 2 lines 64-67 continued in lines 1-8 in column 3). The art of record also taught standardizing different parameters of the polymer, such as molecular weight, viscosity, concentration, particle size, etc.(see columns 5-8 in Whalen et al).

At the time of the invention, it would have been obvious to modify the composition of Okada et al and prepare compositions that have different polymers or different therapeutic proteins, such as fibronectin and have molecular weight of 10,000-100,000 and have 5 to 50% polymer concentration and comprised

biocompatible solvents, such as ethanol or DMSO and deliver the composition to a tissue with a catheter with a reasonable expectation of success. An artisan would have used fibronectin in the composition because such would have allowed adhesion of the embolizing composition to vascular tissue wall.

3. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (571) 272-0735 . The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for TC 1600 is (703) 872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (571) 272-0532.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632

RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER